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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,767	04/07/2005	Rajinder Singh	02-438-B1	9966

20306 7590 11/06/2006

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

FREISTEIN, ANDREW B

ART UNIT PAPER NUMBER

1626

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/530,767

Applicant(s)

SINGH ET AL.

Examiner

Andrew B. Freistein

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-35 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-27, 30 and 35 is/are rejected.
- 7) ☒ Claim(s) 25-35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/7/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 10/12/2006 was entered. Claims 25-35 and 38-41 are pending. Claims 1-24 and 36-37 were cancelled.

Priority

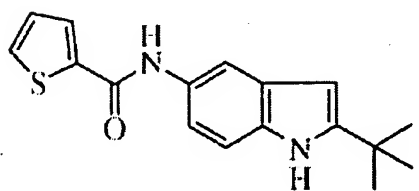
This application is a 371 of PCT/US03/32947, filed 10/15/2003.

Information Disclosure Statement

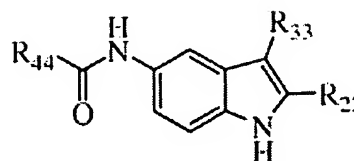
Applicant's information disclosure statement (IDS), filed on 04/07/2005, has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Restriction Requirement

In a response filed 10/12/2006, Applicant elected compound 281,



, and the genus of the formula



wherein R_{22} , R_{33} and R_{44} are as defined in claim 25.

According to MPEP 1850,

When the Markush grouping for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the

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commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

The fact that the alternatives of a Markush grouping can be differently classified should not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

When dealing with alternatives, **if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the examiner.** Reconsideration does not necessarily imply that an objection of lack of unity shall be raised (emphasis added).

In the instant case, there is at least one Markush alternative that is not novel over the prior art. As a result the claims will be restricted as follows:

Status of the Claims

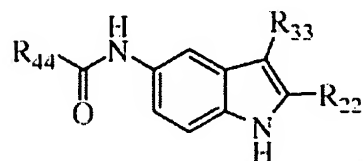
Claims 25-35 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:

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Compositions comprising compounds of the Formula (I),

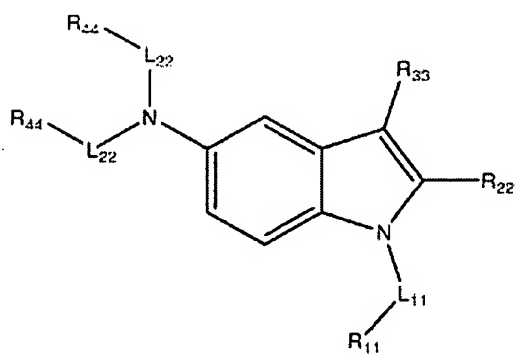


, wherein:

 R_{22} and R_{33} are as defined in claim 25; and R_{44} is optionally substituted C_{3-7} heterocycloalkyl containing at least one N, O or S atom.Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:

Compositions comprising compounds of the Formula



(I), , wherein:

 L_{11} is carboxyl; R_{11} is phenyl or C_{4-6} -heteroaryl;Each L_{22} is independently carboxyl, C_{1-4} alkyl, C_{1-4} alkylC(O);

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Each R₄₄ is independently

H, optionally substituted C₁₋₆ alkyl, optionally substituted C₃₋₇ cycloalkyl, optionally substituted C₃₋₇ heterocycloalkyl containing at least one N, O or S atom, C₃₋₇ cycloalkanone, optionally substituted C₃₋₇ monocyclic or C₇₋₁₃ bicyclic aryl, optionally substituted C₃₋₆ monocyclic or C₅₋₁₃ bicyclic heteroaryl containing at least one N, O, or S atom, or optionally substituted C₃₋₆ monocyclic or C₅₋₁₃ bicyclic heterocycle containing at least one N, O, or S atom, wherein said optional substitutions are one to four R⁶ groups;

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 25-35 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as thiophene, furan, phenyl, pyridine, cyclopropane, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

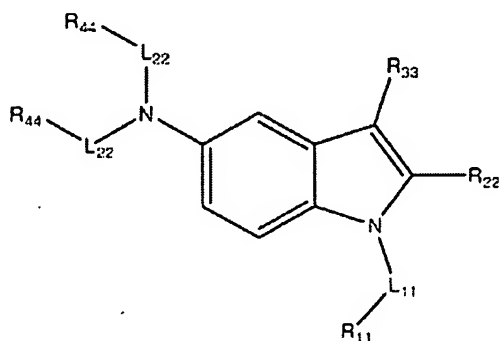
A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-27, 30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al., WO 98/06402.

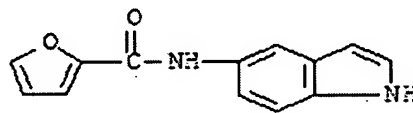
The instant invention is drawn to a composition comprising a compound of the



formula (I),

, wherein L^{11} is a covalent bond; R^{11} is

H; R^{22} is H; R^{33} is H; L^{22} is a bond; R^{44} is H; the other L^{22} is a carboxyl group; and the other R^{44} is a C_{3-6} monocyclic heterocycle containing an oxygen atom.



Johnson et al. disclose the compound

(see

Johnson et al., STN International, HCAPLUS Database, Columbus, OH, Accession No. 1998:124013, Reg. No. 201857-66-1). Examiner presumes that this compound is in a solvent, which creates a composition.

Claim Objections

Claims 25-35 are objected to as being drawn to non-elected subject matter.

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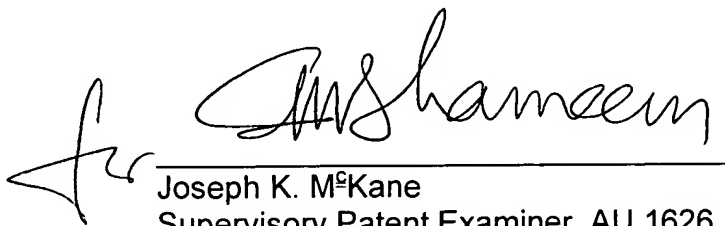
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein
Patent Examiner, AU 1626



Joseph K. M^cKane
Supervisory Patent Examiner, AU 1626
Date: November 2, 2006